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IAP20 Rec'd PCT/PTO 07 APR 2006
Attorney Docket No. : 018872.00167

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IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Applicant	:	Andrew R. GORRINGE, et al.
International Application. No.	:	PCT/GB2004/004274
International Filing Date	:	08 October 2004
Priority Date	:	09 October 2003
Title of the Invention	:	MODIFIED WHOLE CELL, CELL EXTRACT AND OMV-BASED VACCINES

INFORMATION DISCLOSURE STATEMENT

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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith a PTO/SB/08a, a copy of the International Search Report, a copy of the United Kingdom Search Report, and copies of the information listed thereon. Copies of the cited U.S. Published Patent Applications are not submitted in accordance with 37 CFR 1.98(a)(2). The International Search Report and issued in connection with an International patent application that is a counterpart of the above-identified U.S. patent application. The United Kingdom Report and issued in connection with a United Kingdom (GB) patent application that is a counterpart of the above-identified U.S. patent application.

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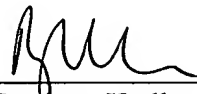
Applicants respectfully request that the information listed on the enclosed PTO/SB/08a form be considered and entered of record in this application.

Each item of information contained in the information disclosure statement is being submitted concurrently with the filing of the above-identified patent application. Therefore, pursuant to 37 C.F.R. §1.97(b)(1), no fee is required. However, if it is found that any fee is occasioned by this Information Disclosure Statement, the Commissioner is hereby authorized to deduct the fee from Deposit Account No. 08-2442 of the undersigned.

Respectfully submitted,
HODGSON RUSS LLP
Attorneys for Applicants

Date: April 7, 2006

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	Filing Date			
	First Named Inventor	Gorringer		
	Art Unit			
	Examiner Name			
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U.S.PATENTS						
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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20030059444	A1	2003-03-27	Zollinger, et al.	
	2	20030022292	A1	2003-01-30	Gray-Owen, et al.	

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FOREIGN PATENT DOCUMENTS								
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	1	WO 2004/014417	WO	A	2004-02-19	Glaxosmithkline Biologicals SA		<input type="checkbox"/>
	2	WO 03/051379	WO	A	2003-06-26	Health Protection Agency		<input type="checkbox"/>

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3	0273116	EP	A2	1988-07-06	Max-Planck-Gesellschaft zur Förderung...	<input type="checkbox"/>
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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	PEETERS, C.C.A.M., et al., "Phase I Clinical Trial With a Hexavalent PorA Containing Meningococcal Outer Membrane Vesicle Vaccine", Vaccine, July 1996, pp. 1009-1015, volume 14, number 10, Butterworth Scientific, Guildford, GB.	<input type="checkbox"/>
	2	BOULTON, Ian C., et al., "Neisserial Binding to CEACAM1 Arrests the Activation and Proliferation of CD4+ T Lymphocytes", Nature Immunology, March 2002, pp. 229-236, volume 3, number 3, Nature Publishing Group.	<input type="checkbox"/>
	3	COHEN, M.S., et al., "Human Experimentation With Neisseria gonorrhoeae: Progress and Goals", The Journal of Infectious Diseases, March 1999, pp. S375-S379, volume 179, suppl. 2, The Infectious Diseases Society of America.	<input type="checkbox"/>
	4	VAN DER LEY, Peter, et al., "Construction of Neisseria meningitidis Strains Carrying Multiple Chromosomal Copies of the porA Gene For Use in the Production of a Multivalent Outer Membrane Vesicle Vaccine", Vaccine, 1995, pp. 401-407, volume 13, number 4, Butterworth Scientific, Guildford, GB.	<input type="checkbox"/>
	5	VAN DER LEY, Peter, et al., "Construction of Multivalent Meningococcal Vaccine Strain Based on the Class 1 Outer Membrane Protein", Infection and Immunity, August 1992, pp. 3156-3161, volume 60, number 8, American Society for Microbiology, Washington, U.S.	<input type="checkbox"/>
	6	WIERTZ, E.J.H.J., et al., "T-Cell Response to Outer Membrane Proteins of Neisseria meningitidis: Comparative Study of the Opa, Opc, and PorA Proteins", Infection and Immunity, January 1996, pp. 298-304, volume 64, number 1, American Society for Microbiology, Washington, U.S.	<input type="checkbox"/>
	7	WEDEGE, Elisabeth, et al., "Antibody Specificities and Effect of Meningococcal Carriage in Icelandic Teenagers Receiving the Norwegian Serogroup B Outer Membrane Vesicle Vaccine", Infection and Immunity, July 2003, pp. 3775-3781, volume 71, number 7, American Society for Microbiology, Washington, U.S.	<input type="checkbox"/>
	8	CLAASSEN, I., et al., "Production, Characterization and Control of a Neisseria meningitidis Hexavalent Class 1 Outer Membrane Protein Containing Vesicle Vaccine", Vaccine, July 1996, pp. 1001-1008, volume 14, number 10, Butterworth Scientific, Guildford, GB.	<input type="checkbox"/>

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9	NORMARK, Staffan, et al., "Gonococci Cause Immunosuppression by Engaging a Coinhibitory Receptor on T Lymphocytes", Nature Immunology, March 2002, pp. 210-211, volume 3, number 3, Nature Publishing Group.	<input type="checkbox"/>
10	GRAY-OWEN, S.D., et al., "CD66 Carcinoembryonic Antigens Mediate Interactions Between Opa-Expressing Neisseria gonorrhoeae and Human Plasmacytoid Phagocytes", The EMBO Journal, June 1997, pp. 3435-3445, volume 16, number 12, Oxford University Press.	<input type="checkbox"/>
11	KUPSCH, E.M., et al., "Variable Opacity (Opa) Outer Membrane Proteins Account For the Cell Tropisms Displayed by Neisseria gonorrhoeae For Human Leukocytes and Epithelial Cells", The EMBO Journal, February 1993, pp. 641-650, volume 12, number 2, Oxford University Press.	<input type="checkbox"/>
12	DEHIO, C., et al., "The Role of Neisserial Opa Proteins in Interactions With Host Cells", Trends in Microbiology, December 1998, pp. 489-495, volume 6, number 12, Elsevier Science.	<input type="checkbox"/>
13	GRANT, C.C.R., et al., "Proteoglycan Receptor Binding by Neisseria gonorrhoeae MS11 is Determined by the HV-1 Region of OpaA", Molecular Microbiology, April 1999, pp. 233-242, volume 32, number 2, Blackwell Science Ltd.	<input type="checkbox"/>
14	VAN PUTTEN, J.P.M., et al., "Binding of Syndecan-Like Cell Surface Proteoglycan Receptors is Required for Neisseria gonorrhoeae Entry Into Human Mucosal Cells", The EMBO Journal, May 15, 1995, pp. 2144-2154, volume 14, number 10, Oxford University Press.	<input type="checkbox"/>
15	GRAY-OWEN, S.D., et al., "Differential Opa Specificities for CD66 Receptors Influence Tissue Interactions and Cellular Response to Neisseria gonorrhoeae", Molecular Microbiology, December 1997, pp. 971-980, volume 26, number 5, Blackwell Science Ltd.	<input type="checkbox"/>
16	BOS, M.P., et al., "Carcinoembryonic Antigen Family Receptor Recognition by Gonococcal Opa Proteins Requires Distinct Combinations of Hypervariable Opa Protein Domains", Infection and Immunity, April 2002, pp. 1715-1723, volume 70, number 4, American Society for Microbiology, Washington, U.S.	<input type="checkbox"/>
17	BILLKER, O., et al., "The Structural Basis of CAECAM-Receptor Targeting by Neisserial Opa Proteins", Trends in Microbiology, June 2000, pp. 258-260, volume 8, number 6, Elsevier Science Ltd.	<input type="checkbox"/>
18	BOS, M.P., et al., "Differential Recognition of Members of the Carcinoembryonic Antigen Family by Opa Variants of Neisseria gonorrhoeae", Infection and Immunity, June 1997, pp. 2353-2361, volume 65, number 6, American Society for Microbiology.	<input type="checkbox"/>
19	De JONGE, M.I., et al., "Conformational Analysis of Opacity Proteins From Neisseria meningitidis", European Journal of Biochemistry, November 2002, pp. 5215-5223, volume 269, number 21, FEBS.	<input type="checkbox"/>

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20	VIRJI, M., et al., "The N-Domain of the Human CD66a Adhesion Molecule is a Target for Opa Proteins of Neisseria meningitidis and Neisseria gonorrhoeae", Molecular Microbiology, December 1996, pp. 929-939, volume 22, number 5, Blackwell Science Ltd.	<input type="checkbox"/>
21	TOLEMAN, M., et al., "Expression of Pathogen-Like Opa Adhesins in Commensal Neisseria: Genetic and Functional Analysis", Cellular Microbiology, 2001, pp. 33-44, volume 3, number 1, Blackwell Science Ltd.	<input type="checkbox"/>
22	MUENZNER, P., et al., "Carcinoembryonic Antigen Family Receptor Specificity of Neisseria meningitidis Opa Variants Influences Adherence to and Invasion of Proinflammatory Cytokine-Activated Endothelial Cells", Infection and Immunity, June 2000, pp. 3601-3607, volume 68, number 6, American Society for Microbiology.	<input type="checkbox"/>

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Examiner Signature		Date Considered	
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2006-04-07
Name/Print	Ranjana Kadle	Registration Number	40041

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**